

REMARKS

Applicants respectfully request the scheduling of a telephone interview with the Examiner before the mailing of another office action.

Status of the Claims

Claims 3 to 5, 7 to 13, 18, 22 to 24, 26, 27, and 34 to 39 were acted upon by the Examiner in the Office Action, dated October 31, 2006. Claims 18 and 34 to 39 have been amended. No claims have been canceled. No claims have been added. Accordingly, claims 3 to 5, 7 to 13, 18, 22 to 24, 26, 27, and 34 to 39 are presented for examination.

Summary of the Examiner's Action

Claim Rejections

Claims 3 to 5, 7 to 13, 18, 22 to 24, 26, 27, and 34 to 39 stand rejected under 35 U.S.C. §112, first paragraph (written description).

Claims 7 to 13, 22 to 24, 26, and 34 to 39 stand rejected under 35 U.S.C. §103(a), as being unpatentable over Crespo (WO 97/33975, wherein the English version is US 6,248,588) in view of Engler (US 2003/0211598).

Claims 3 to 5, 7 to 13, 18, 22 to 24, 26, 27 and 34 to 38 stand rejected under 35 U.S.C. §103(a), as being unpatentable over Crespo taken with Engler and further in view of Rolland (US 6,040,295) or Sene (WO 98/02522, wherein its English version is US 6,451,256).

Applicants respectfully traverse the Examiner's rejections.

Discussion

Amendments to the Claims

Claims 18 and 34 to 39 have been amended to recite a composition "consisting of...". Claims 18 and 34 to 38 have been amended to remove reference to the amount of time the recombinant adenovirus vectors or particles are stored.

No new matter has been added to the application.

The 35 U.S.C. §112, First Paragraph, Rejections

Claims 3 to 5, 7 to 13, 18, 22 to 24, 26, 27, and 34 to 39 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner asserts that the specification lacks support for storage temperatures “from about 4°C to about 20°C” and “for at least 3 months to about 8.5 months”. Claims 18 and 34 to 39 have been amended to recite a composition “consisting of...”. In view of this amendment, applicants have also amended claims 18 and 34 to 38 to remove reference to the amount of time the recombinant adenovirus vectors or particles are stored.

Applicants have previously cited support for the recitation “a temperature from about 4°C to about 20°C” in Example 6 (page 33, line 29 to page 36, line 13) and Figure 11 of the application. Applicants respectfully submit that support for this recitation is also found in other parts of the application:

Page 1, lines 10-12, which recites (emphasis added):

The invention relates to compositions comprising a recombinant adenovirus vector and a concentration of human serum albumin (HSA) effective to stabilize the adenovirus vector at a temperature above the freezing point of water...

Page 2, line 33 to page 3, line 2, which recites (emphasis added):

Thus, in a first embodiment, the invention provides a composition comprising a recombinant adenovirus vector and a concentration of serum albumin effective to stabilize the adenovirus vector at a temperature above the freezing point of water...

Page 4, lines 17 to 19, which recites (emphasis added):

In one embodiment, the temperature is greater than or equal to 4°C and less than 37°C. In a further embodiment, the temperature is greater than or equal to 20°C. Preferably, when the temperature is greater than 4°C...

Page 14, lines 32-34, which recites (emphasis added):

In one embodiment, the temperature is greater than or equal to 4°C and less than 37°C. In a further embodiment, the temperature is greater than or equal to 20°C. Preferably, when the temperature is greater than 4°C...

Applicants submit that it would be clear to one of skill in the art that applicants were in possession of the temperature range “from about 4°C to about 20°C”. The four passages above

all indicate that applicants envisioned their invention to encompass temperatures above 4°C. In addition, Example 6 provides data for the temperatures of 4°C and 20°C. The presence of data for these two temperatures would put the skilled artisan on notice that applicants were in possession of not only these two points but also all those points in between. The skilled artisan would not expect the results of experiments performed at the temperatures of 5°C, 6°C... 18°C and 19°C, etc. to differ significantly from applicants' results for the temperatures of 4°C and 20°C. The disclosures and data of the present application taken together with the knowledge of the skilled artisan, clearly indicate that applicants were in possession of the claimed range.

Accordingly, Applicants respectfully request that the rejection of claims 3 to 5, 7 to 13, 18, 22 to 24, 26, 27, and 34 to 39 under 35 U.S.C. §112, first paragraph (written description), be withdrawn.

The 35 U.S.C. §103(a) Rejections

Claims 7 to 13, 22 to 24, 26, and 34 to 39 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Crespo in view of Engler et al. Applicants respectfully traverse the rejection.

The present amendments have been provided in order to move prosecution forward as applicants maintain their previous assertions that the previous obviousness rejections are deficient.

With regard to a *prima facie* obviousness rejection, MPEP §2143 states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Accordingly, a proper *prima facie* case of obviousness requires that the combination teach all of the claim limitations. Applicants submit that the present rejection has not satisfied this requirement.

Presently amended claims 18 and 34 to 39, from which all of the other pending claims depend directly or indirectly, recite “a composition ***consisting of*** ...”

Applicants submit that neither Crespo nor Engler et al. disclose a composition ***consisting of*** the compositions of claims 18 and 34 to 39.

The solutions of Crespo all require a gelatin solution (see column 2, line 64, to column 3, line 62). In contrast, claims 18 and 34 to 39 do not require gelatin. Engler et al., which relates to delivery-enhancing agents and has been cited for the teaching of a Tris-HCl buffer, provides no basis to remove the gelatin from the solutions of Crespo. Accordingly, the combination of Crespo and Engler et al. does not disclose the compositions of presently amended claims 18 and 34 to 39.

Accordingly, Applicants respectfully request that the rejection of claims 7 to 13, 22 to 24, 26, and 34 to 39 under 35 U.S.C. §103(a) as being unpatentable over Crespo in view of Engler et al. be withdrawn.

Claims 3 to 5, 7 to 13, 18, 22 to 24, 26, 27 and 34 to 38 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crespo taken with Engler et al. and further in view of Rolland et al. (US 6,040,295) and Sene (WO 98/02522, wherein the English version is US 6,451,256).

Applicants respectfully traverse the rejection.

Rolland et al. discloses compositions and methods for enhancing the uptake of nucleic acids by cells or organisms and has been cited for its teaching of an isotonic solution comprising 150 mM NaCl. Sene discloses methods for preserving viral particles in a sucrose solution and has been cited for its teaching of Tris-HCl buffer with pH between 8 and 9.

For the reasons noted above, claims 7 to 13, 22 to 24, 26, and 34 to 39 are non-obvious in view of the combination of Crespo and Engler et al. Rolland et al. and Sene provide no basis to overcome the deficiencies of this combination.

Accordingly, Applicants respectfully request that the rejection of claims 3 to 5, 7 to 13, 18, 22 to 24, 26, 27 and 34 to 38 under 35 U.S.C. §103(a) as being unpatentable over Crespo taken with Engler et al. and further in view of Rolland et al. and Sene be withdrawn.

In re Application of Shian-Jiun Shih, et al.
Application No. 09/763,210

S&L File No. P27073 USA
February 28, 2007
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A favorable action on the merits is requested respectfully. It is hereby requested that the term to respond to the Office Action dated October 31, 2006, be extended one month, from January 31, 2007 to February 28, 2007. Payment to cover the extension fee has been submitted electronically. The Commissioner is hereby authorized to charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 19-5425.

Respectfully submitted,

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